

Data Access Agreement for Work to be Performed by Organizations of the MINZDRAV (Russian Ministry of Health; Federal Department for Medical, Biological and Extreme Problems) and MINATOM (Russian Ministry of Atomic Energy) under the Agreement Between the Government of the Russian Federation and the Government of the United States of America on Cooperation in Research on Radiation Effects for the Purpose of Minimizing the Consequences of Radioactive Contamination on Health and the Environment (JCCRER Agreement)

Project 1.2b

STOCHASTIC EFFECTS OF ENVIRONMENTAL RADIATION EXPOSURE IN POPULATIONS LIVING NEAR THE MAYAK INDUSTRIAL ASSOCIATION

INTRODUCTION

The purpose of this data access agreement is to ensure that Russian and American scientists working on projects under the Agreement Between the Government of the Russian Federation and the Government of the United States of America on Cooperation in Research on Radiation Effects for the Purpose of Minimizing the Consequences of Radioactive Contamination on Health and the Environment (JCCRER Agreement) have equal access to all primary and original Russian and American data necessary to conduct the work described under Directions 1 and 2 of the JCCRER Agreement. Such access will ensure the highest quality of scientific research conducted in an atmosphere of mutual trust and cooperation.

GENERAL PROVISIONS

1. For the purposes of this agreement on data access, data is defined as all information, in whatever format or media, that is identified by the Principal Investigators and Directors of Participating Institutes as necessary to carry out the project.
2. Privacy statutes in Russia and the United States generally restrict access to data which includes personal identifiers. Individual data, however, is the basis of much of the research work of the JCCRER. Therefore, where necessary, adherence to these statutes will be ensured by substituting unique numerical identifiers which protect individual privacy while allowing analysis of individual and aggregate data.
3. Data covered by this access agreement include original or raw data, compiled data created before these projects were begun, and second generation or summarized data and information compiled according to project requirements. The specific project agreement provisions will specify the actual data which fall under each of these categories. Appropriate access to all these data must be ensured; however, original or raw data, and compiled data created before these projects were begun remain the property of that organization and that country where the data were obtained and are currently maintained.

4. Secondary data created as part of JCCRER projects, which are a joint scientific product, will be jointly owned by the Russian and the American institutions participating in the project. Each project will determine what is a scientific product of the collaboration and therefore subject to joint ownership.
5. Project participants have the right to appropriate access to original, compiled and secondary data on the territory of the organization which owns and maintains the data.
6. The specific project agreement provisions will identify the kind and extent of unpublished primary, compiled and secondary data that may be transferred out of the country of ownership to achieve specific project goals such as technical analyses, modeling, etc. at the home institution of researchers. When such data transfers occur, they must also be approved in writing by the Director of the institute or organization to which the data belong. Transferred data cannot be used for purposes other than those specified by the agreement, even after the project is completed or the researcher is no longer associated with the JCCRER. In cases where such data are transferred to people who are not participants in the project for the purposes of furthering the project, the same conditions and limitations on use of data apply. Such transfers will be carefully scrutinized.
7. No transfers, publications, presentations, press releases or any other form of communication to the outside world regarding details of the unpublished data or the unpublished results of studies conducted under the authority of the JCCRER will be made without the written consent, and participation of the institutions maintaining the data sets and the scientists involved in the research. Any agreement to make data publicly available must be approved by the Directors of organization performing the research. Scientists and specialists participating as current members of the JCCRER Joint Committee, Executive Committee and Scientific Review Groups have a right to review data and unpublished results of studies as appropriate to their responsibilities but are similarly bound by the restrictions on communication as described in this paragraph.
8. Dissemination of scientific results, in the form of presentations at scientific meetings and publications in referred journals, is regarded as an essential product of the JCCRER work. To ensure that such communications take place while complying with the requirements of the participating institutions and funding agencies, procedures will be developed for the expeditious review and approval of such communication requests from the principal investigators.
9. Data published in the open, peer-reviewed literature shall be referenced and used according to generally understood and accepted conventions of scientific conduct; it is expected that proper reference and credit to the origin of the published material will be made.
10. After the publication of reports, third parties may request access to unpublished study data that does not contain individual identifiers, in order to conduct independent analyses. Third parties are defined as experts in the fields of radiation health effects and dosimetry who

are not part of any JCCRER project. Procedures will be developed for requesting and approving such third party access to primary data.

PROJECT 1.2b DATA ACCESS AGREEMENT: SPECIFIC PROVISIONS

INTRODUCTION

The objective of the long-term epidemiologic studies is to assess stochastic (carcinogenic) effects among populations exposed to offsite releases of radioactive materials from the Mayak nuclear facility. The unique conditions in the South Urals resulted in chronic exposure of the residents to a wide range of radiation doses. An investigation focusing on health effects observed over the 40-year period since the onset of exposure could become a source of new knowledge about the health risks associated with chronic radiation exposure.

A cohort study design will be used in this project to evaluate stochastic health effects among populations exposed to offsite releases from Mayak. The analysis of stochastic effects carried out in previous studies of these populations was based on mortality data from the 33-year follow-up of the Techa Cohort comprising 29,000 individuals: 26,000 exposed in adolescence and adulthood and 3,000 exposed in utero. The rate of leukemia and certain solid cancers was slightly higher among exposed persons. A significant disadvantage of those studies was loss to follow-up of 36% of the cohort members due to migration. Only 70% of the known deaths were confirmed by death certificates which led to a considerable uncertainty in the inferences about the significance of exposure effects. In order to obtain more complete data, a decision was made to continue the study along the following two lines. The first is to obtain more complete information on vital status for the entire cohort, and, for all deaths, to obtain an official document confirming the fact of death for migrants; on the basis of the new information to re-assess the cancer mortality rates among the exposed cohort. The second is to assess cancer incidence among the sub-cohort of exposed non-migrant subjects from the Techa River cohort.

PERSONS WITH RIGHTS OF ACCESS TO PROJECT 1.2b DATA

In addition to those specified in item 7 of the General Provisions, above, as having access to the data, the Russian and American Principal Investigators for Project 1.2b, along with the database manager at URCRM, will have complete access to all types of data as described below. These include raw data on hard copy files which contain identifying information, and computerized files. Access to these data sources is essential in carrying out the research mission of this study.

Other study participants (primarily URCRM scientific staff) as identified by the principal investigators will have access to computerized data files that are relevant to projects on which they are currently working, and which are essential to data analysis and interpretation for these individual projects. Both the Principal Investigators and other study participants will have access to the local area computer network at URCRM.

All raw data, including copies of paper records and master computerized data files, should remain at URCRM. Analyses and work involving these records should only be conducted at URCRM.

DATA COVERED BY THIS ACCESS AGREEMENT

The data covered by this agreement are described below. However, it is understood that this agreement extends to all raw data that form the basis of the data bases or data files and to all data, data files, and data bases that may be created in the future in the course of fulfillment of agreed upon work for Project 1.2b.

Original Data

This category covers raw data on individuals and includes information on a variety of health and exposure parameters. This information is contained on paper forms and is stored at the Urals Research Center for Radiation Medicine (URCRM). These data contain personal identifying information. These data are owned solely by the URCRM and include the case histories which are stored in the URCRM archives, death certificates, and clinical records on all cancer diagnoses.

Compiled Data Created Before the Beginning of Project 1.2b

This category includes information on individuals for a variety of health and exposure parameters that are computerized into a number of separate computer files. These computerized data also contain individual identifying information. These include the following data:

- Techa cohort registry including exposed residents of villages located on the Techa River
- information on cancer and leukemia morbidity (notifications of first-diagnosed cancer cases, case histories, out-patient charts, blood and tissue samples, protocols on cytologic and morphologic preparations) for the period from 1951 through 1995, which served as the basis for compiling computer files "CR_REG."
- information on all-cause mortality which was used to set up computer files "DTH_REG" (death certificates, autopsy protocols) on Chelyabinsk Oblast residents included in the registry for the period from 1945 through 1992, and on Kurgan Oblast residents for the period from 1950 through 1993.
- dosimetry file data contained in the computer file "DOSES".
- information from the exposed population registry computer file "REG/BASE1"

- information from the Techa Cohort Registry computer file "CR_REG/KOG/kog97"

Data Compiled for this Project

This category includes data tabulations prepared from the computerized files. These are summary data files on a variety of demographic, health and exposure characteristics for which all identifying information has been deleted.

The following data should be regarded as a scientific product of the collaboration and are subject to joint ownership:

- the report including description of methods used to collect information and conduct analyses of cancer morbidity
- tables on study cohort parameters
- descriptive analyses of non-cancer mortality for the study cohort based on tabulated data presented by defined characteristics
- tables presenting cancer morbidity matched against cancer mortality
- descriptive analyses and reports on cancer morbidity among cohort members
- jointly prepared publications on the issues researched in the framework of Project 1.2b

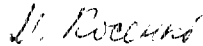
DATA THAT MIGHT BE REMOVED FROM THE COUNTRY OF ORIGIN

Working data files, which are subsets of the master data files and will be used for specific analyses, may be shared by the Principal Investigators for Project 1.2b. These can be in the form of computer disks or other appropriate electronic media (including data sharing via the Internet) and would allow data analyses to be conducted by the Principal Investigators both in Russia (at URCRM) and in the United States. Information to be included on the working data files will be jointly agreed upon by the Principal Investigators and handled as described in item 6 of the General Provisions, above.

Unpublished, summarized data may be sent or taken to the U.S. for the purpose of finishing and submitting joint progress reports to financial sponsors or for submitting joint publications to peer-reviewed scientific journals.

APPROVALS

Mira Kossenko



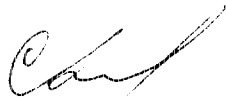
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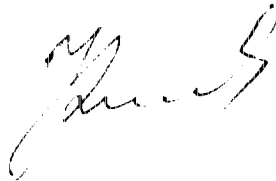
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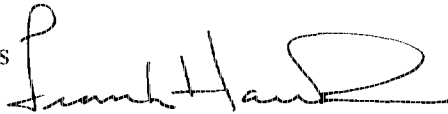
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